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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,518	08/24/2001	Mark J. Jaroszeski	93004	2429
21901	7590	06/14/2007		
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			EXAMINER ANGELL, JON E	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/939,518	Applicant(s) JAROSZESKI ET AL.	
	Examiner J. Eric Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,8,10,21,22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,8,10,21,22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/2/07 has been entered.

Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are currently pending and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 8, 10, 21, 22, 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,678,558 B1 (Dimmer et al.).

Dimmer teaches a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field (claims 1, 21) or a plurality of substantially continuous electric fields (claim 24) in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell (claims 1, 21, 24); wherein the duration of the applying step is in the range of 200ms to 100 sec (claims 2 and 22); wherein the electric field comprises a square, bipolar, or sinusoidal pulse waveform (claims 6, 25) and wherein the electric field comprises a pulse comprising a combination of at least two of the indicated pulse waveforms (claim 26); wherein the injection step is by syringe injection (claims 8, 27); wherein the target tissue is skin or tumor tissue (claims 10, 28).

Specifically, Dimmer et al. teaches a method for delivering an agent such as a nucleic acid into a cell of a target tissue (such as skin or tumor tissue) using an electric signal that has a bipolar waveform (e.g., see abstract), wherein the agent is injected directly by needle and syringe (e.g., see column2 lines 24-27), wherein the electric signal can have a bipolar, square or sinusoidal waveform (e.g., see column 5, lines 35-36; column 8, lines 17-30), wherein the electric signal can be a plurality of electric signals (e.g., see column 9, lines 10-16) wherein the electric field(s) are in the range of 1mV/cm to 200V/cm (e.g., 25V/cm or 100V/cm see column 10, lines 29-42); wherein the electric field is applied for a duration of 200ms-20minutes (e.g., most preferably about 50 μ s-400ms see column 10, lines 54-60). (Also see column 13, lines 7-7-

Art Unit: 1635

19; column 14, lines 21-23; column 23, lines 1-11; column 24, lines 43-50; column 29, lines 12-15; claims 1, 10, 11, 16, 17, 25).

Dimmer also teaches applying an agent movement signal having a potential of about 5V-200V and more preferably about 10V-100V, having a duration of the agent movement signal of preferably about 100 μ s-10 seconds. Therefore, Dimmer teaches administration of an electric signal that meets the voltage and duration limitations of the claims. As such, the administration of the "agent movement signal" as described by Dimmer, would necessarily have the same result as the claimed method. In other words, since the agent movement signal taught by Dimmer meets the voltage and duration limitations of the claims it must have the same effect on the cells. Thus, application of the agent movement signal, as described by Dimmer would necessarily result in a change in the porosity of the cell sufficient to facilitate entry of the desired molecule into the cell.

Applicant is reminded that MPEP 2112.01 teaches, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"

Therefore, Dimmer et al. anticipates the instant claims.

Response to Arguments

2. Applicant's arguments filed 5/2/07 have been fully considered but they are not persuasive.

Applicants argue that instant claims 1, 21 and 24 are limited to a “continuous electric field...” and assert that this means a *single* electric pulse in the range and duration indicated.

In response, it is respectfully pointed out that that claim 1 is drawn to a method that “consists essentially of... applying... an electric field consisting of a single continuous electric field...”. It is respectfully noted that MPEP 2111.03 states:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355.

Since there is no evidence in the specification or claims that the presence of additional electric pulses would materially affect the basic and novel characteristic of the claimed method, the phrase “consisting essentially of” can be construed as equivalent to “comprising”. Therefore, the claim is not, necessarily limited to a single electric pulse as asserted by Applicants. Furthermore, it is pointed out that claims 21 and 24 are drawn to a method “comprising... applying a continuous electric field...” (claims 21), “wherein the applying step comprises applying a plurality of substantially continuous electric pulses...” (claim 24). Therefore, claims 21 and 24 are clearly not limited to applying only a single electric pulse, but also explicitly encompass applying a “plurality of substantially continuous electric pulses”.

Applicants argue that Dimmer does not teach applying an electric field consisting of a single continuous electric field in the range of 1mV/cm to 200V/cm for a duration of 200ms to 20 minutes. Rather, applicants contend, Dimmer describes applying an electroporation signal having a total electroporation signal duration that is preferably less than about 10 seconds, more preferably about 30μs-10 seconds, even more preferably about 30μs-1ms and most preferably

about 50 μ s-400ms, wherein the total electroporation signal duration is comprised of the individual durations of each of the plurality of therapeutic electrical signals within the electroporation signal, wherein each of the plurality of therapeutic electrical signals has a pulse duration of less than about 50 μ s.

In response, it is respectfully pointed out that the instant claims are not necessarily limited to applying a single electric field, as assert by applicants, but may comprise applying additional electric fields, for the reasons indicated above.

Applicants contend that the Office is improperly combining the parameters of the "total electroporation signal duration" and the "therapeutic electrical signals" as described by Dimmer to arrive at the claim limitations of the instant invention. Applicants assert that therapeutic electrical signals, as described by Dimmer at col. 10, line 11-19, preferably have a pulse duration of less than about 50 μ s, more preferably have a pulse duration of less than about 12.5 μ s and most preferably a pulse duration of less than about 5 μ s.

In response, it is respectfully pointed out that Applicants are focusing on the "preferable" pulse duration. As previously indicated, and acknowledged by the Applicants, Dimmer explicitly indicates, and claims that the total electroporation signal duration is preferably less than about 10 seconds, more preferably about 30 μ s-10 seconds, even more preferably about 30 μ s-1ms and most preferably about 50 μ s-400ms (see column 10, lines 50-59; claim). Furthermore Dimmer teaches and explicitly claims that the therapeutic electric signal is comprised of 1 to 1,000,000 pulses (e.g., see claim 5). Also see col. 10, lines 60-61 which explicitly indicates "when the electroporation signal includes pulse, the total number of bipolar pulses is preferably 1 to 1,000,000." Therefore, although Dimmer may indicate that the

preferable duration of the therapeutic signal is less than about 50 μ s, Dimmer does contemplate that the "total signal duration" is most preferably about 50 μ s-400ms. Since Dimmer explicitly teaches that the number of therapeutic signals can be 1 (see claim 5), Dimmer does indicate that the total signal duration of a single therapeutic signal can be for a duration of about 50 μ s-400ms.

Applicants argue that the agent movement signal taught by Dimmer does not affect a change in porosity of the cell, thus it does not anticipate the claims. Applicants argue that claim 1 is a process claim not a product claim and assert that the Office has not properly applies MPEP 2112.01 and should apply the guidelines of MPEP 2112.02.

In response, the method steps of applying the agent movement signal taught by Dimmer, meet all of the steps of the claimed method. As such, the agent movement signal must result in the same outcome as the claimed method, regardless of whether or not Dimmer recognized the recognized the outcome (MPEP 2112.01). It is noted that there is no indication in MPEP 2112.01 that it applies only to products, as applicants appear to indicate.

Conclusion

3. No claim is allowed.
4. This is a RCE of applicant's earlier application. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case.

Art Unit: 1635

See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
AU 1635